VERTACONNECT Ⓣ – Spinal Implant

Device description:
VERTACONNECT Ⓣ is a hollow structural frame. The upper and lower aspects of the implant are open. Surface spikes assist in the positive anchorage and seating of the implant between the vertebral bodies. The device is available in a variety of sizes enabling the surgeon to choose the size best suited to the individual pathology and anatomical condition.
The implant is available in 15 different sizes. There are three different lengths: 31/34/37 mm. The posterior heights are 8/10/12 mm. With the integrated rotatable expanding element in the anterior end two lordotic angles (3° or 11° and 7° or 15°) can be set. This enables anterior heights of between 9 and 19 mm.
The VERTACONNECT Ⓣ TLIF cage is made of a titanium alloy (Ti-6Al-4V) in accordance with ASTM F136.

Indications for use:
The VERTACONNECT Ⓣ TLIF cage is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation and is intended for use with autograft to facilitate fusion.

Contraindications:
- Use of these systems is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Anomalous bone density, osteoporosis or osteomalacia that prevents stable anchorage of the implant
- Spinal tumours
- Infections
- Signs of local inflammation
- Fever or leukocytosis
- Allergy or intolerance to implant material
- Myelopathic focus in the fused segment (only for titanium alloy implants)
- Spondylolisthesis ≥grade 3
- Prior fusion at the level(s) to be treated.
- Surgical conditions that rule out any potential benefit from spinal surgery (such as severe damage to bone structures at the implantation site, badly distorted anatomy due to anomalies, inadequate tissue coverage)
- Medical conditions that could prevent successful implantation (e.g. obesity, mental disorders, pregnancy, paediatric cases, patients in poor general health, systemic or metabolic diseases, substance abuse, senility, lack of patient compliance)
- Cases that are not mentioned under Indications

Caution:
- These implants are intended for single use only and should not be re-implanted.
- Federal law restricts this device to sale by or on the order of a physician.

Complications:
The patient should be informed of the following possible complications:
- Haematoma
- Pain
- Implant impaction
- Local or systemic infection
- Paraplegia
- Damage to local structures
- Implants can break when subjected to the increased loading associated with delayed union or nonunion
- Loss of fixation, subsidence, or expulsion of the implant
- Pseudoarthrosis/loss of fusion
- Vascular lesion
- Adjacent Segment Disease
- Death

Precautions:
1. These implants are supplied sterile. Do not use if sterile packaging is opened or damaged. These devices are intended for single use only. Do not re-implant, re-sterilize, reprocess or reuse.
2. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level and other patient conditions which may impact the performance of the system
3. Throughout the entire procedure particular care must be exercised to protect nerve roots.
4. Carefully check and remove any bone splinters following resection.
5. Prior to implantation, check the required implant size.
6. Do not use excessive force to introduce the implants.
7. The selection of size and implantation of the implant remain the exclusive responsibility of the user surgeon who must be experienced in spinal surgery.
8. Intraoperative levering must be prevented in all circumstances!
9. To ensure safe use with no levering motion, use the product specific instrumentation.
10. It is imperative that dissimilar metals do not come into contact in vivo. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment.
11. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

Warnings:
- The spinal implants are intended for single use only and may not be reused. Reuse can cause implant failure, infections and/or death.
- The attending physician is responsible for establishing the indication, selecting the implant and carrying out the implantation procedure, and must be experienced as well as trained in the requisite surgical technique.
- The general surgical procedure can be learned out of the surgical technique described in the product information. This document can be obtained from SIGNUS or the representative.
- Implant components and instruments not belonging to the system must not be used.
- Instruments specially developed by SIGNUS are available for application of the implants. These ensure safe application.
- Prior to surgery, ensure that the instruments belonging to the system are sterile and fit for purpose.
- Prior to implantation, examine the implant for integrity and check the given size with the instruments for comparison.

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SIGNUS The Spine Sign®

- Before surgery, the patient must be informed of all possible risks and complications that can arise in connection with the intervention itself and from use of the implant, as well as of postoperative behavior.
- The operation must be carried out under fluoroscopy. The correct position of the implant system used must be verified radiographically.
- The implant must not be scratched or notched, as this can lead to a reduction in mechanical stability.
- The implant should be placed on the anterior and support the posterior portion of the cortical ring, but may cannot be placed beyond it. The VERTACONNECT Ⓣ can be implanted in an unspread condition and can be spread in the disc space. The drive shaft must be pushed into the expansion element up to the stop. The rotation of the expansion element for adjusting the lordotic angle can be controlled via a removable optical display. The implantation instruments must first be removed, when the position of the VERTACONNECT Ⓣ is secured.
- The implants must not be used as stand-alone devices but rather must be combined with a spinal fixator cleared for use in the US.
- All implant components used, must be documented in the patient file with item numbers, name and lot number.
- Aftercare must be tailored to the individual patient's requirements and must be determined by the treating physician. After the intervention, the patient should be allowed only very limited physical activity. This applies in particular to the lifting of loads, rotating movements and all kinds of sporting activities. Falls and sudden jerking movements of the spine must be avoided.
- In the postoperative phase, special care must be taken to ensure that the patient is given all the necessary information by the treating physician according to his individual requirements.

How supplied:
Sterilization is done by radiation (gamma rays).
The implants are packaged individually under sterile conditions and must be kept in the original packaging until used.
Before use, check that the expiry date has not been exceeded and that the sterile packaging is intact.
Caution: Do not use if the sterile packaging has been opened or damaged.
The associated instruments are provided clean but not sterile. Instruments are provided in an autoclavable tray. All instruments must be disassembled (if applicable) and cleaned before sterilization and introduction into a sterile surgical field.

Cleaning:
During use, keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. Thoroughly clean all instruments as soon as possible after use. Implant inserters must be disassembled prior to cleaning.

Pre-Cleaning:
Manual pre-cleaning is performed to remove gross contaminants. Presoak the surgical devices for a minimum of 3 minutes in cold water. All movable components must be repeatedly mobilized under running water, until no visible contamination remains. Brush all exposed surfaces with a nylon bristle brush.
Instruments with cavities as well as joints, threads, hinges and springs have to be rinsed inside and outside by water spray gun at a pressure of 58 psi (4 bar) for a minimum of 20 seconds using cold water. Surfaces have to be brushed with a soft brush until visible contaminations are removed completely.

Automated cleaning:
Automated cleaning is the preferred cleaning method. Manual cleaning (above) should be performed prior to using automated cleaning equipment. Instruments have to be placed in the instrument tray of the purifier/disinfector (e.g. Miele G7735). Instruments with cannula must be placed in the tray for micro-invasive surgery (MIS) instruments and must be connected to the spray nozzle system.
Clean the instruments by using a program with analogue parameters (e.g. Vario TD):
- Minimum 2 min pre washing with cold tap water
- intermediate rinsing
- Under 55°C, for 5 min cleaning with Neodisher FA forte, 0.5% (Miele, Princeton NJ) or alternative cleaning with a adequate purifier
- 3 min neutralization with tap water
- intermediate rinsing
- 2 min rinsing with demineralized water

Disinfection:
Manual disinfection:
Disinfect the instruments by using an FDA cleared disinfectant (VAH-list of the Association of applied Hygiene). Cavities as well as joints, threads, hinges and springs must be water-rinsed inside and outside.

Automated operation:
Automated thermal disinfection, at a maximum temperature of 93°C in the purifier / disinfector (part of the above mentioned Vario TD program) is performed under consideration of national requirements regarding the thermal disinfection performance of the equipment in use (e.g. A0-Value according standard EN ISO 15883-1).

Drying:
Manual drying:
Dry the instrument with a fluff-free fabric. Cavities as well as joints, threads, hinges and springs have to be dried by compressed air. Also, the application of a vapor-permeable lubricant, suitable for steam sterilization based on paraffin/white-oil basis, should be used on moving parts.

Automated operation:
Drying of the Instrument in the purifier/disinfector (one drying cycle, part of the Vario TD program) if applicable, the instrument can be dried by a fluff-free fabric. Cavities as well as joints, threads, hinges and springs have to be dried by compressed air. The application of a vapor-permeable lubricant, suitable for steam sterilization based on paraffin/white-oil basis, should be considered at these parts, too.
After cleaning/disinfecting, the disassembled instruments should be re-examined for visible soil. If visible soil is found, repeat the cleaning process. Following re-examination, the instruments should be dried using a soft cloth and placed in their proper locations in the instrument cases. The disassembled inserter components are reassembled by introducing the threaded inserter shaft into the cannulated outer shaft until the two pieces are engaged.

Inspection:
Unless marked otherwise, instruments may be reused after reprocessing and sterilization. Before each reuse, inspect instruments including inaccessible areas, joints and moving parts for possible damage, wear or non-functioning parts. Carefully inspect the critical, inaccessible areas, joints and all movable parts. Damaged or defective instruments should not be used or processed. Contact your local sales representative for repair or replacement.

Sterilization:
Sterilization validation studies have shown that the following recommendations for instrument sterilization are effective to an SAL of 10^{-6}.
The use of an FDA approved sterilization wrap is recommended.

Method:	Steam
Cycle:	pre-vacuum
Temperature:	270°F (132°C)
Exposure Time:	4 minutes
Drying Time:	30 minutes

MRI Safety Information:
The safety and compatibility of VERTACONNECT Ⓣ in an MRI environment was not determined. The product has not been tested with regard to heating, migration or artefact formation in an MRI environment.

USA: Federal law restricts the sale of this device by or on the order of a physician

Product Guarantee:
SIGNUS Medizintechnik GmbH guarantees that each individual spinal implant is manufactured with the greatest of care and from selected material. The entire process, from manufacture to final packaging, is under constant quality control. However, given that SIGNUS Medizintechnik GmbH has no influence over the selection or use of the implant, the diagnosis of the patient or the surgical technique used, or the handling of the implant following dispatch from our company, no guarantees can be given regarding a successful surgical result or the lack of complications.